

**Amendment**

Applicant(s): Sheridan et al.

Serial No.: 09/727,739

Confirmation No.: 4181

Filed: December 1, 2000

Title: SOMATOSTATINS AND METHODS

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**Claim Objections**

Claims 1-3 and 12-14 remain objected to for minor informalities, as they allegedly recite unselected subject matter (amino acid sequences SEQ ID NOs: 2, 16, 17 and 19). This objection is respectfully traversed, for reasons set forth below relating to the scope of examination. Reconsideration and withdrawal of the claim objection is respectfully requested.

**Examiner Interview Summary**

Applicants' Representative Victoria A. Sandberg appreciates Supervisory Patent Examiner Yvonne Eyler's time in discussing the above-identified patent application on April 17, 2003. In said telephone interview between Examiner Eyler, Victoria A. Sandberg, and Nancy A. Johnson (also of Mueting, Raasch & Gebhardt, P.A.), all claims were discussed but an agreement was not reached with respect to the claims.

The conversation centered on Applicants' concern that the scope of examination has been narrower than it should have been in view of the Restriction Requirement mailed on October 4, 2001. A number of different options for review of the Restriction Requirement, and its subsequent implementation, were discussed. One option suggested by the Examiner and set forth in the Interview Summary mailed April 22, 2003, was to file a Request for Continued Examination specifically claiming the subsequences and setting forth an argument that their treatment was unclear and should be specifically considered and examined or restricted in some manner.

After consideration of the alternatives, Applicants are filing this Request for Continued Examination and an amended claim set to request a more complete examination of the claimed subject matter to which they believe they are entitled in view of the Restriction Requirement issued in this application.

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Scope of Examination

The objection to claims 1-3 and 12-14 for minor informalities was maintained in the Advisory Action mailed April 8, 2003. The Examiner contends that the amended claims recite unselected subject matter, namely SEQ ID NOs:2, 16, 17 and 19. This objection is respectfully traversed.

Applicants contend that this objection is rooted in an improper implementation of the Restriction Requirement mailed October 4, 2001, and request that the scope of examination be expanded to include all properly elected subject matter. This is not a request for withdrawal or modification of the Restriction Requirement *per se*. Rather, the Examiner is requested to expand the examination so that it is consistent with the Restriction Requirement presently of record in this application.

*Restriction requirement*

At paragraph 1 of the Restriction Requirement mailed October 4, 2001, the Examiner identified three inventions:

- I. Claims 1-3 and 12-15, drawn to somatostatin polypeptides
- II. Claims 4-6, drawn to polynucleotides
- III. Claims 7-11, drawn to a method of identifying a modified somatostatin polypeptide.

Applicants elected invention I, claims 1-3 and 12-15, directed to somatostatin polypeptides.

*Species election*

At paragraph 8 of the Restriction Requirement mailed October 4, 2001, the Examiner identified three patentably distinct species of the claimed invention, identified herein as A, B and C for ease of reference, as follows:

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A. Corresponding to PPSS-I: SEQ ID NO:8 (a nucleotide sequence) encoding SEQ ID NO:3 (a polypeptide sequence)

B. Corresponding to PPSS-II: SEQ ID NO:14 (a nucleotide sequence) encoding SEQ ID NO:9 (a polypeptide sequence)

C. Corresponding to PPSS-II": SEQ ID NO:20 (a nucleotide sequence) encoding SEQ ID NO:15 (a polypeptide sequence)

The Examiner stated: "Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable." The Restriction Requirement continues by advising the Applicant of his rights upon the allowance of a generic claim.

Applicants properly responded to the requirement by electing species C (SEQ ID NO:20 encoding SEQ ID NO:15) and providing a list of all claims readable thereon, which included the elected claims (claims 1-3 and 12-15) as well as unelected claims (claims 4-6 and 7-11, corresponding to Groups II and III).

To explain why Applicant included claim 15 (directed to the polypeptide of claim 13 wherein the first amino acid sequence comprises SEQ ID NO:6 or SEQ ID NO:18) as reading on the elected species (SEQ ID NO:20 encoding SEQ ID NO:15), Applicants pointed out that SEQ ID NO:18 is wholly included in the elected species (the same cannot be said for SEQ ID NO:6, which is wholly included in unelected species SEQ ID NO:8 encoding SEQ ID NO:3).

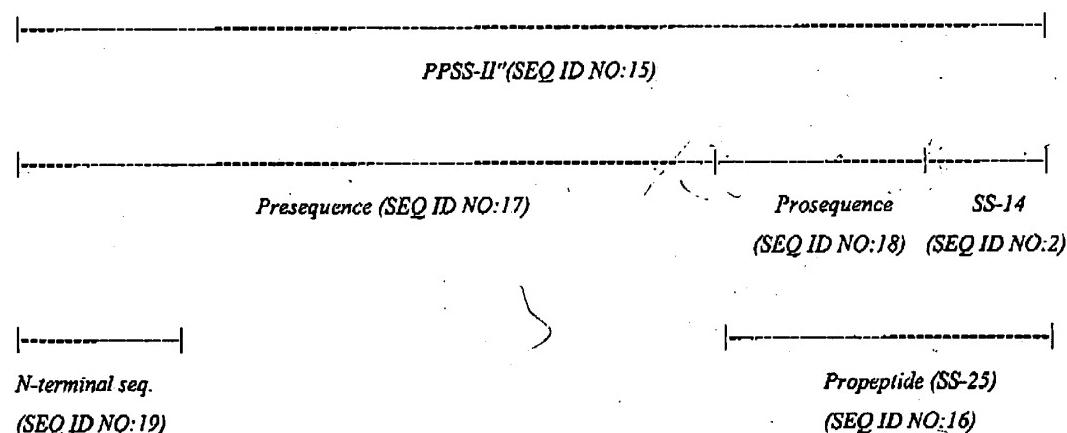
Claim 1 (as amended in the Response to the Restriction Requirement to correct a typographical error in the sequence identification number) recited "a portion of ... SEQ ID NO:3" (a nonelected species) and "a portion of ... SEQ ID NO:15" (an elected species). The elected claims depending from claim 1 (as originally filed) recited SEQ ID NOs:1-7, 9-13, 15 and 17-19 (claim 2) and SEQ ID NOs:3-7, 9-13, 15 and 17-19 (claims 3). Applicants point out that the Applicant was *not asked to make a species election among these polypeptide subsequences*. The only species election required was based on the sequences relating to the

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different somatostatin families: PPSS-I polypeptides, the PPSS-II' polypeptides, and the PPSS-II" polypeptides (species A, B and C described above).

As noted above, sequences corresponding the PPSS-II" family (SEQ ID NO:20 encoding SEQ ID NO:15) were elected. SEQ ID NOs:2, 16, 17, 18 and 19 are subsequences of SEQ ID NO:15 and, in Applicants' view, should be under examination in the present prosecution pursuant to the species election. However, the Examiner characterizes SEQ ID NOs:2, 16, 17 and 19 as non-elected subject matter. On what basis were these subsequences excluded from examination? Applicants submit that these subsequences cannot be excluded from examination if the Applicants never had an opportunity to elect them. To hold otherwise would mean that the Examiner has made a *de facto* election for the Applicants, which Applicants contend is not permitted.

To assist the Examiner in understanding the relationships among SEQ ID NO:15 and its subsequences, the following diagram is provided:

**Invention I (somatostatin polypeptide)/Species C (SEQ ID NO:15)**

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In summary, Applicants submit that, within the context of the invention of group I (claims 1-2 and 12-15), amino acid subsequences SEQ ID NOs:2, 16, 17, 18 and 19 should be examined in addition to the full length amino acid sequence SEQ ID NO:15. Applicants request that the scope of examination be broadened to include this subject matter, thereby insuring that pending claims 1-3 and 12-15 are accorded a full and complete examination. If the pending claims are not allowed in the next Office Action, Applicants further request that the Action be made non-final to allow sufficient opportunity for Applicants to respond to any additional arguments raised by the Examiner.

Summary

It is believed that the claims are presently in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to contact Applicants' Representative at the below-listed number if it is believed that prosecution of the above-identified patent application can in be assisted or expedited thereby in any way.

Respectfully submitted for

Sheridan et al.

By

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